

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Kaddurah-Daouk, R. *et al.*

Serial No.: 10/695265

Filed: October 27, 2003

For: METHODS FOR DRUG DISCOVERY,  
DISEASE TREATMENT, AND DIAGNOSIS  
USING METABOLOMICS

Attorney Docket No.: MBZ-001CP

Group Art Unit: 1637

Examiner: Not Yet Assigned

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

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10/28/04  
Date of Signature and of Mail Deposit

By:

Elizabeth A. Hanley, Esq.  
Registration No. 33,505  
Attorney for Applicant

INFORMATION DISCLOSURE STATEMENT

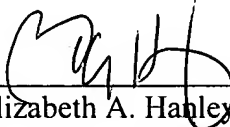
Dear Sir:

The present application is a Continuation-in-part Application of U.S. Serial No. 09/835119, filed April 13, 2001 (Atty. Docket No. MBZ-001). Reference ID Nos. A2, A3, A5-A7, A9, A11-A17, A19, A21, A25, B1-B8, B10-B11, B13-B21, B26, C1-C5, C7-C12, C20-C22 listed on the enclosed PTO Form 1449 have been previously cited by or submitted to the Office in the prior application, and, in accordance with 37 CFR §1.98(d), copies of these references are not enclosed herewith, but will be provided upon request. Furthermore, copies of cited U.S. patents and U.S. publications (Reference ID Nos. A1, A4, A8, A10, A18, A20, A22-A24) are not enclosed with this statement.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicant understands that the Examiner will make an independent evaluation of the cited publications.

Under 37 CFR § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,  
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MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Re: U.S. Patent Application No.: 10/695265  
For: METHODS FOR DRUG DISCOVERY, DISEASE TREATMENT, AND  
DIAGNOSIS USING METABOLOMICS  
Inventor: Kaddurah-Daouk, R. *et al.*  
Filed: October 27, 2003  
Our Ref. No.: MBZ-001CP

Dear Sir:

I enclose herewith for filing in the above-identified application the following:

1. Information Disclosure Statement;
2. PTO Form 1449;
3. Copies of selected references cited in PTO Form 1449 (20); and
4. A Return Postcard.

No additional costs are believed to be due in connection with the filing of this Information Disclosure Statement. However, please charge any necessary fees in connection with the enclosed statement to our Deposit Order Account No. 12-0080. For this purpose, a duplicate of this sheet is attached.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: MS Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450:

10/28/03  
Date

Elizabeth A. Hanley, Esq., Reg. No. 33,505

Respectfully submitted,  
LAHIVE & COCKFIELD, LLP

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Attorney for Applicant

APPLICANT FACSIMILE OF FORM PTO-1449

REV 7-80

U.S. DEPARTMENT OF  
COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY DOCKET NO

MBZ-001CP

SERIAL NO

10/695265

LIST OF PUBLICATIONS CITED BY APPLICANT  
(Use several sheets if necessary)

APPLICANT

Kaddurah-Daouk, R. et al.

FILING DATE

October 27, 2003

GROUP

1637

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	4,511,659	04/85	Matson	436	150	
1	A2	4,863,873	09/89	Matson	436	63	
1	A3	5,104,639	04/92	Matson	424	2	
	A4	5,541,310	07/96	Ward et al.	536	23.6	
1	A5	5,565,323	10/96	Parker et al.	435	6	
1	A6	5,824,467	10/98	Mascarenhas	435	4	
1	A7	5,977,083	11/99	Burcoglu	514	44	
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							YES	NO
1	A25	WO 86/03006 A1	05/86	WO				

## OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

	A26	Avery et al. "The use of lipid metabolic profiling to assess the biological impact of marine sewage pollution." <i>Arch Environ Contam Toxicol</i> . 1998 Aug;35(2):229-35
	A27	Brindle et al. "Rapid and noninvasive diagnosis of the presence and severity of coronary heart disease using H-NMR-based metabonomics." <i>Nat Med</i> . 2002 Dec;8(12):1439-44
Examiner		Date Considered
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-80	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO <b>MBZ-001CP</b>	SERIAL NO <b>10/695265</b>
LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT <b>Kaddurah-Daouk, R. et al.</b>	
		FILING DATE <b>October 27, 2003</b>	GROUP <b>1637</b>

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
1	B1	WO 92/13273 A1	08/92	WO				
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1	B3	WO 96/23075 A1	08/96	WO				
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1	B7	WO 99/37786 A2, A3	07/99	WO				
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	B22	Buchholz <i>et al.</i> "Metabolomics: quantification of intracellular metabolite dynamics." <i>Biomol Eng.</i> 2002 Jun;19(1):5-15
	B23	Glassbrook <i>et al.</i> "Metabolic profiling on the right path." <i>Nat Biotechnol.</i> 2000 Nov;18(11):1142-3
	B24	Holmes <i>et al.</i> "Metabonomic characterization of genetic variations in toxicological and metabolic responses using probabilistic neural networks." <i>Chem Res Toxicol.</i> 2001 Feb;14(2):182-91
	B25	Matsumoto <i>et al.</i> "A new chemical diagnostic method for inborn errors of metabolism by mass spectrometry – rapid, practical, and simultaneous urinary metabolites analysis." <i>Mass Spectry Rev</i> 1998;15(1):43-57
1	B26	Nicholson, J.K. <i>et al.</i> 'Metabonomics': understanding the metabolic responses of living systems to pathophysiological stimuli via multivariate statistical analysis of biological NMR spectroscopic data'. <i>Xenobiotica</i> 1999 Nov;29(11):1181-9
Examiner		Date Considered
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-83	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO <b>MBZ-001CP</b>	SERIAL NO <b>10/695265</b>
LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)		APPLICANT <b>Kaddurah-Daouk, R. et al.</b>	
		FILING DATE <b>October 27, 2003</b>	GROUP <b>1637</b>

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		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
1	C1	WO 01/23601 A2, A3	04/01	WO				
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1	C3	WO 01/40896 A2, A3	06/01	WO				
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1	C20	WO 02/09836 A2	02/02	WO				
1	C21	WO 02/22857 A2	03/02	WO				
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	C23	Ning <i>et al.</i> "Gas chromatographic-mass spectrometric metabolic profiling of patients with fatal infantile mitochondrial myopathy with de Toni-Fanconi-Debre syndrome." <i>Acta Paediatr Jpn.</i> 1996 Dec;38(6):661-6
	C24	Rashed <i>et al.</i> "Screening blood spots for inborn errors of metabolism by electrospray tandem mass spectrometry with a microplate batch process and a computer algorithm for automated flagging of abnormal profiles." <i>Clin Chem.</i> 1997 Jul;43(7):1129-41
	C25	Trethewey <i>et al.</i> "Metabolic profiling: a Rosetta Stone for genomics?" <i>Curr Opin Plant Biol.</i> 1999 Apr;2(2):83-5
	C26	'Biochemicals Organic Compounds and Diagnostic Reagents.' In <u>Sigma Catalog</u> . 1996, p.253
Examiner		Date Considered
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